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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/998,195	12/03/2001	Chris H. Senanayake	4821-409-999	4449

20582 7590 02/09/2005

JONES DAY
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EXAMINER

KUMAR, SHAIENDRA

ART UNIT PAPER NUMBER

1621

DATE MAILED: 02/09/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/998,195	SENANAYAKE ET AL.	
	Examiner	Art Unit	
	SHAIENDRA - KUMAR	1621	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 January 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8 and 32-43 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8 and 32-43 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 1/18/05 has been entered.

Claims 1-8 and 32-43 are pending in this application.

Claim Rejections - 35 USC § 103

2. Claims 1-8 and 32-43 are rejected under 35 U.S.C. 103(a) as being unpatentable over combined teachings of Jeffery et al, Jerussi et al (US 6,331,571) and Fang et al (Tetrahedron Asymmetry, 1999).

Jeffery et al teach structurally similar compounds as claimed herein. See page 2583, compound 4 and 5a. Compound 5 expressly suggest stereoisomerisms similar to claimed herein. The difference between the reference and herein claimed compounds is the hydroxy substituent at different positions.

Jerussi et al is teaching structurally similar compounds as claimed herein, which have different stereoisomerisms, as claimed herein, see column 30, lines 45-50 and column 28, lines 50-55. The difference between the reference and herein claimed compounds is that the reference compounds do not have hydroxy substituent. Also note the reference teach method of preparing enantiomer, see column 27, lines 40-50.

Likewise, Fang et al is teaching preparation of enantiomerically pure sibutramine and its metabolite, which is similar to prepared in the instant specification.

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to obtain compounds of Jeffery et al having hydroxy substituents in different positions, and obtain enantiomers using the process of Jerussi et al and Fang et al, with the reasonable expectation of achieving a successful enantiomers and their pharmaceutical compositions, absent evidence to the contrary. Note that positional isomers are prima facie obvious. In re Norris (CCPA 1950) 179 F2d 970, 84 USPQ 458.

Applicants' arguments were fully considered and are not found convincing. Applicants argue that a prima facie obvious has not been established, as the three basic criteria have not been met. Applicants have failed to point out as to what criteria have not been met. At the out set, there was no combination of prior art used in the previous rejection. Applicants' arguments that stereoisomerisms have not been taught by Jeffery is not convincing. See compound 5a. Also see Jerussi et al and Fang et al, which expressly teach the enantiomers and the process of preparing enantiomers. Applicants' arguments that Jeffery disclose that the pharmacological activity of sibutramine is mediated predominantly by sibutramine metabolites other than those claimed in this application is of little if any probative value inasmuch as the reference teach structurally similar compounds and its enantiomers. Applicants argue that the Jeffery teach that their compounds are pharmacologically inactive. The examiner did not find such

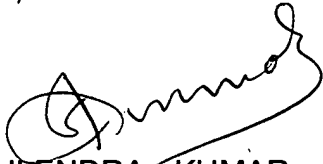
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statement in the reference. Notwithstanding that, Jerussi et al and Fang et al expressly teach that sibutramine are pharmacologically active.

3. Any inquiry concerning this communication or earlier communications from the examiner should be directed to SHAILENDRA - KUMAR whose telephone number is (571)272-0640. The examiner can normally be reached on Mon-Thur 8:00-5:30, Alt Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on (571)272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



SHAILENDRA - KUMAR
Primary Examiner
Art Unit 1621

S.Kumar
2/7/05